

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF MASSACHUSETTS

United States of America  
ex rel. Jeffrey J. Bierman,

Plaintiff,

v.

Orthofix International N.V., et al.,

Defendants.

Civil Action No. 05-10557 (RCL)

United States of America  
ex rel. Marcus Laughlin,

Plaintiff,

v.

Orthofix International, N.V., et al.,

Defendant.

(formerly Civil Action No. 1:08-cv-11336  
(JLT))

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS RELATOR  
MARCUS LAUGHLIN'S SECOND AMENDED COMPLAINT**

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Relator Marcus Laughlin's Second Amended Complaint (the "SAC") should be dismissed. Despite four prior opportunities, the SAC—like Relator's prior pleadings—still fails to plead essential elements of all of Relator's fraud claims with the specificity required by Federal Rule of Civil Procedure ("Rule") 9(b), fails to allege facts to support the required elements of his claims, and relies on theories of liability that have no basis in law. As for the forty-seven new counts under state and local false claims acts, the SAC offers no more than boilerplate recitations of the elements of the claims and thus fails to satisfy any of Rules 9(b), 8(a), or 12(b)(6). For all these reasons, the SAC should be dismissed, and because Relator has now had four chances to state a claim, to no avail, the SAC should be dismissed with prejudice.

### INTRODUCTION

Orthofix International N.V. is the parent and sole shareholder of Orthofix Inc., ("Orthofix").<sup>1</sup> Orthofix manufactures and supplies medical devices, including the bone growth stimulators ("BGS") that are the subject of Relator's SAC. Relator briefly served as a Director of National Accounts for Orthofix from late 2005 until his termination on January 16, 2006. SAC ¶¶ 12, 13.

Relator filed his Original Complaint on March 23, 2006 in the U.S. District Court for the Northern District of Texas. No. 1:08-cv-11336-JLT, Dkt. No. 2 (D. Mass. Mar. 23, 2006). The complaint was filed under seal and alleged violations of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"), as well as wrongful termination. Relator filed his First Amended Original Complaint (the "FAC") on June 3, 2008. FAC, No. 1:08-cv-11336-JLT, Dkt. No. 29 (D. Mass.

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<sup>1</sup> Relator adds Orthofix, Inc. as a party for the first time in the SAC. But, as the docket shows, Relator has not served the SAC on Orthofix, Inc. Therefore, Relator's SAC must be dismissed as to Orthofix, Inc. not only on all the grounds set out below, but also due to insufficient service of process and lack of personal jurisdiction. Rule 4(h); *Omni Capital Int'l, Ltd. v. Wolff & Co.*, 484 U.S. 97, 104 (1987) (holding that federal courts cannot exercise personal jurisdiction over a defendant without proper service of process).



June 3, 2008). Subsequent to this filing, and while still under seal, the case was transferred to the U.S. District Court for the District of Massachusetts and consolidated with *United States ex rel. Bierman v. Orthofix International N.V., et al.* No. 1:05-cv-10557 (D. Mass.).

On May 5, 2009, the United States declined to intervene, and the Court ordered the pleadings unsealed. *See* Order, Dkt. No. 26. However, instead of serving his pleading, Relator Laughlin then sought an additional 120 days to evaluate whether to amend further. Rel.'s Mot. to Extend Time, Dkt. No. 28. Although the 120 days were granted, Relator ultimately chose not to amend, and instead served Orthofix with the Original Complaint on September 9, 2009, which Orthofix then moved to dismiss on December 4, 2009.<sup>2</sup> In that motion, Orthofix argued that Relator's FCA claims failed to allege violations of any federal program reimbursement or coverage rule and were devoid of the factual specificity required by Rule 9(b). Mot. to Dismiss Am. Compl. at 5–18, Dkt. No. 91. Orthofix similarly contended that Relator had failed to sufficiently allege the elements of his remaining Sherman Act and wrongful termination claims. *Id.* at 18–22. Relator both opposed Orthofix's motion and in the alternative sought leave to amend. Rel.'s Resp. to Mot. Dismiss Compl., Dkt. No. 102. This Court then granted leave to amend, Dkt. No. 120, over Orthofix's opposition, Opp. to Rel.'s Mot. to Am. Compl., Dkt. 116, and Relator filed the SAC on June 23, 2010.<sup>3</sup>

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<sup>2</sup> Although Relator served Orthofix with his Original Complaint, not his FAC, Orthofix moved to dismiss the more comprehensive FAC, which encompassed all the allegations of the Original Complaint. Mot. to Dismiss Am. Compl. at 3, n.2., Dkt. No. 91.

<sup>3</sup> Like the Affidavit he attached to his Response to Motion To Dismiss and Motion for Leave To Amend, Dkt. 102, Relator's SAC also purports to refer to a number of exhibits (A–F) that, once again, are not attached to the SAC, have never been filed with the Court, and have not been served on Orthofix. To the extent a reference to any of these alleged exhibits is intended to support the SAC, it must be disregarded in evaluating whether the SAC survives this Motion to Dismiss. *See Trans-Spec Truck Serv., Inc. v. Caterpillar Inc.*, 524 F.3d 315, 321 (1st Cir. 2008) (in reviewing a motion to dismiss, a “court may properly consider only facts and documents that are part of or incorporated into the complaint”).

## ARGUMENT

Relator now seeks relief under a set of FCA-based theories nearly identical to those he pled in his FAC, and adds 47 boilerplate counts under 27 state and local false claims acts. Relator fails, however, to state a claim under any of his 56 “Counts.”<sup>4</sup> First, Relator’s fraud-based allegations (Counts 1–5 and 7–56) remain, as in prior pleadings, completely devoid of the specificity required to satisfy Rule 9(b)—they neither provide the circumstances of any alleged fraud, nor identify a single false claim submitted or a false representation used in connection with a planned false claim. Furthermore, Relator’s claims also fall short of satisfying more basic pleading requirements, either failing to identify any federal program reimbursement or coverage rules that Orthofix’s alleged conduct violated (Counts 1–3, 8–9), or simply failing to allege required elements of the causes of action they rely upon (Counts 4–9). In addition, Relator’s claims based on an alleged “rental requirement” (Count 1) are jurisdictionally barred. Finally, Relator’s claims under state and local false claims acts (Counts 10–56) not only are inadequate under Rules 8 and 9(b), but they also fail to satisfy procedural prerequisites of those acts.<sup>5</sup>

### I. COUNTS 1–5 AND 7–56 SHOULD BE DISMISSED BECAUSE RELATOR HAS NOT PLED WITH THE SPECIFICITY REQUIRED BY RULE 9(B)

The FCA imposes liability upon persons who (1) present or cause to be presented to the United States government a claim for approval or payment, where (2) that claim is false or

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<sup>4</sup> Although Relator presents Counts 8 and 9, SAC ¶¶ 62–73, as independent FCA claims, they simply parrot the language of FCA sections 3729(a)(1) and 3729(a)(2), respectively, and are presumably intended to embrace the substantive theories alleged in Counts 1–5. SAC ¶¶ 39–54. Accordingly, this memorandum will not separately address Count 8 or 9.

<sup>5</sup> The SAC also occasionally refers to allegedly improperly retained overpayments made by certain *private* payors. *See, e.g.*, SAC ¶¶ 17, 23, 25, 26, 30, 34. However, none of the SAC’s fifty-six counts relies upon these allegations, and, apart from pure speculation that the alleged actions might also have had some nexus to (unspecified) government healthcare programs, *see* SAC ¶ 23, these allegations are made only as to *private* payors and pertain only to *contract-driven* payment. They therefore cannot provide any basis for an FCA claim and will not be addressed further in this motion.

fraudulent, and (3) the action was undertaken with actual knowledge of the falsity of the information contained in the claim, or in deliberate ignorance or reckless disregard of the truth or falsity of that information. 31 U.S.C. § 3729(a)(1); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004). It also prohibits the use of “false” records in support of claims upon the government, and conspiracy to submit false claims. 31 U.S.C. § 3729(a)(2)–(3).

As these elements make clear, FCA claims are claims of fraud, and Rule 9(b) requires that the circumstances constituting fraud be alleged with particularity. Fed R. Civ. P. 9(b); *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009); *Karvelas*, 360 F.3d at 230, 233. Furthermore, Rule 9(b)’s requirements apply equally to Relator’s fraud-based state and local claims. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 n.8 (1st Cir. 2007). As a result, in this Circuit as in others, Relator must at a minimum set forth “the who, what, where, and when of the allegedly false or fraudulent representation,” including allegations of specific false claims submitted or false representations made. *Gagne*, 565 F.3d at 45 (quoting *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004)); *see also, Rost*, 507 F.3d at 731.

A. Counts 1–5 and 7–56 Should Be Dismissed Because They Do Not Allege the Circumstances of Any Fraudulent Conduct with the Particularity Required By Rule 9(b)

When alleging an FCA violation, a relator must identify, with particularity, the circumstances of the alleged fraud or intended fraud. Those circumstances include what item or service was billed or intended to be billed; what payment was sought; the identity of those involved; the time and place of any misconduct; and why the provider was prohibited from submitting a claim for that care in that amount. *Karvelas*, 360 F.3d at 230, 233; *Gagne*, 565 F.3d at 47.

Despite clear First Circuit law articulating this straightforward and longstanding pleading burden, Relator's conclusory allegations continue to be devoid of the particularized facts Rule 9(b) requires. While Relator asserts that Orthofix submitted unjustifiably high bills to Medicare, paid healthcare workers to refer business to Orthofix, and conspired with physicians to submit claims for work they did not perform, SAC ¶¶ 42–54, 59–61, Relator has repeatedly failed to plead a single, particularized example of any misconduct. Indeed, even after three briefs from Orthofix specifically identifying these gaps in Relator's prior pleadings,<sup>6</sup> he still has not identified a single physician, medical facility, or Orthofix employee who allegedly engaged in wrongdoing. Nor has Relator specified the time or place of any misconduct—including any specific connection between any “fraudulent” conduct and any of the twenty-six state and local jurisdictions he invokes—or explained how any given claim was false or fraudulent. Because Relator has yet again failed to allege the specific facts necessary to plead even a single instance of fraud with the particularity required by Rule 9(b), Counts 1–5 and 7–56 should be dismissed.

B. Counts 1–5 and 7–56 Should Be Dismissed Because Relator's SAC Does Not Identify Any False Claims That Were Submitted to the Government or Any False Statements Made

In addition to failing to plead the circumstances surrounding the alleged fraud, Relator fails to identify any specific false claims, as also required by Rule 9(b). For example, as a first essential step in claims under section 3729(a)(1) (Counts 1–5, 8), Relator must identify, with particularity, the claims that Orthofix submitted to the government that were allegedly false, including details such as their dates, identification numbers, and amounts. *See Gagne*, 565 F.3d at 46; *see also United States ex rel. Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347, 354 (D. Mass. 1999) (“[P]laintiffs simply allege three methods by which [defendant] is said to have inflated its

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<sup>6</sup> *See* Mot. To Dismiss Am. Compl. at 5–8, Dkt. No. 91; Opp. to Rel.'s Mot. to Am. Compl. at 9–14, Dkt. No. 116; Reply to Rel.'s Resp. to Mot. to Dismiss Am. Compl. at 4–5, Dkt. No. 118.

bills to the government, without citing a single instance of a false claim.”); *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (“Without citing a single false claim . . . Relator has not met even a bare-bones Rule 9(b) test.”). Similarly, for his 3729(a)(2) and (a)(3) claims (Counts 7 and 9), Relator must identify, with particularity, the false or fraudulent representation that Orthofix allegedly made and the details of the planned false claim that was the object of that representation. *Gagne*, 565 F.3d at 46–48. Here, the SAC does not even attempt to identify with specificity *any* fraudulent statement or *any* false claim submitted—or planned to be submitted—to anyone, let alone any false claims that were submitted to a particular federal health care program, or to any particular program in any of the state or local jurisdictions Relator invokes. Because he has thereby failed to satisfy Rule 9(b)’s requirements of, Relator’s fraud-based claims (Counts 1–5 and 7–56) should be dismissed.

## II. COUNTS 1–5 AND 7–9 SHOULD BE DISMISSED BECAUSE THEY DO NOT STATE A CAUSE OF ACTION UNDER RULE 12(B)

While Relator’s failure to satisfy Rule 9(b) alone requires dismissal, Counts 1–5 and 7–9 also suffer from more basic defects warranting dismissal under Rule 12(b)(6). Although a relator is required to provide only “a short and plain statement . . . showing that [he] is entitled to relief,” Rule 8(a) nonetheless requires him to supply the “grounds” for his “entitlement to relief.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In evaluating whether a complaint meets this requirement, a court must disregard the legal conclusions asserted by the complaint and determine whether the remaining well-pleaded factual allegations plausibly give rise to an entitlement to relief. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949–50 (2009); *Twombly*, 550 U.S. at 555. Here, Relator’s Counts 1–5 and 7–9 fall far short of justifying such an entitlement.

A. Counts 1–3 Should Be Dismissed Because Relator’s Conclusory Assertions Do Not Allege Any Legal Violation by Orthofix, and Because Count 1 Is Jurisdictionally Barred

In Counts 1–3, Relator alleges the existence of various legal requirements that he claims would render unspecified claims submitted by Orthofix to the government false, and thus give rise to liability under the FCA. Because these alleged legal “requirements” do not in fact exist, however, Relator cannot rely on them as a basis for any false claim allegations. Moreover, to the extent Relator relies on allegations that Orthofix was required to rent its BGS, the Court is barred from hearing his claims by the FCA’s “first to file” rule. 31 U.S.C. § 3730(b)(5).

1. Count 1 Should Be Dismissed Because Orthofix Is Not Required To Rent Its BGS

In Count 1, Relator asserts that Orthofix submitted false claims to the government when it failed to provide patients with the option to rent its BGS products. SAC ¶¶ 35, 41, 43. But despite Orthofix’s multiple attempts to elicit a basis for Relator’s theory in prior briefings,<sup>7</sup> he has repeatedly failed to identify any law or regulation that imposes an obligation to rent BGS products. He has failed to do so because no such obligation exists.

Bone growth stimulators are covered by Medicare as “Durable Medical Equipment” (“DME”) pursuant to a national coverage determination that has been in effect, in part, since 1980. *See Medicare Nat’l Coverage Determination Manual* § 150.2 (2009). At all times relevant to this action, BGS devices were included in the “inexpensive and other routinely purchased” category of DME (which includes DME “acquired at least 75 percent of the time by purchase”). 42 U.S.C. § 1395m(a)(2)(A)(ii); *see also* 42 C.F.R. § 414.220(a)(2); *Program Memorandum, HCFA Transmittal AB-00-05, Operating Instructions for Expanded Coverage of*

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<sup>7</sup> *See* Mot. To Dismiss Am. Compl., at 13, Dkt. No. 91); Opp. to Rel.’s Mot. to Am. Compl. at 4 n.3 Dkt. No. 116; Reply to Rel.’s Resp. to Mot. To Dismiss Am. Compl. at 3 n.2, Dkt. No. 118.

*the Electrical Osteogenic Stimulator for Fracture Healing*, at 1 (Feb. 2000), available at <http://146.123.140.205/transmittals/downloads/AB000560.pdf> (listing BGS in the “inexpensive and routinely purchased category”). For items in this category, payment is “made on a rental basis or in a lump-sum amount for the purchase of the item.” 42 U.S.C. § 1395m(a)(2)(A); 42 C.F.R. § 414.220(b)(1) (emphasis added). Thus, by their plain terms, the statutes and regulations determining reimbursement specifically do *not* require that BGS be offered for rental. While Relator may disapprove of the BGS reimbursement policy the government has decided upon, he is not free to invent his own, and his “rental requirement” claims must be dismissed.

2. *The Court Lacks Subject Matter Jurisdiction To Hear Relator’s Claims to the Extent They Are Based on a Requirement That Orthofix Rent Its BGS*

Under the FCA, only the *first* relator to bring allegations of misconduct against a defendant is allowed to pursue those claims on behalf of the United States. 31 U.S.C. § 3730(b)(5). In 2005, Jeffrey J. Bierman filed a qui tam suit alleging that certain “defendants,” including Orthofix, violated the FCA by failing to offer their BGS products for rent. Bierman Compl., ¶¶ 48–55, 75–80, Dkt. No. 1. One year later, in 2006, Relator filed his Original Complaint, alleging that Orthofix violated the FCA by failing to offer its BGS products for rent. Orig. Compl. ¶¶ 19, 24, 25, 30, 31, 1:08-cv-11336, Dkt. No. 2. Under the FCA, a “later allegation . . . [that] states all the *essential facts* of a previously-filed claim or the same *elements* of a fraud described in an earlier suit” is precluded. *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 32 (1st Cir. 2009) (citations and internal quotation marks omitted); *see also United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 218 (D.C. Cir. 2003) (barring subsequent suit that alleged “merely variations on the fraud [the first-filed] complaint described”). Given the patent overlap between Bierman’s allegations and Relator’s later-filed claims—acknowledged by Relator himself, who argued in a prior

briefing that his own claims were so “intertwined” with Relator Bierman’s that every aspect of the two cases must be considered together on an identical schedule<sup>8</sup>—Relator’s Count 1 claims must be dismissed.<sup>9</sup>

3. *Count 2 Should Be Dismissed Because Orthofix Was Not Required To Bill Medicare the Lowest Price It Charged to Any Other Customer*

In his second Count, Relator alleges an FCA violation for “[e]ach time Orthofix has submitted, or caused to be submitted, a claim to Medicare, Medicaid or TRICARE for payment for any amount in excess of the lowest price charged by Orthofix for its products.” SAC ¶¶ 41, 44–45. However, despite the multiple pleading opportunities afforded him over the course of this action, Relator still has not identified *any* authority that requires medical equipment suppliers or doctors to bill federal healthcare programs at the lowest price at which they sell their equipment to other buyers.<sup>10</sup>

In fact, neither the Medicare statute nor its implementing regulations contain any provision that requires Orthofix to charge the government the lowest price charged to any customer. Instead, Medicare requires only that “inexpensive and other routinely purchased” DME, such as BGS, be reimbursed at either the “national payment amount” for the item listed on U.S. Department for Health and Human Services, Centers for Medicare & Medicaid Services

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<sup>8</sup> See Rel.’s Resp. to Mot. for Leave To File Reply and to Extend Time ¶ 3, Dkt No. 114.

<sup>9</sup> Relator’s SAC continues to press his wholly inapposite assertion that he is an “original source” of information. See SAC ¶¶ 8–9, 38. Although serving as an “original source” qualifies for an exception to the “public disclosure” bar, 31 U.S.C. § 3730(e)(4), that bar provides a separate and independent limitation on the court’s jurisdiction, see *Duxbury*, 579 F.3d at 16. So even if Relator qualified for an exception to the *public disclosure* bar, his claims would still be precluded by the *first to file* bar.

<sup>10</sup> In fact, in opposing Orthofix’s Motion To Dismiss Relator’s First Amended Complaint, Relator abandoned this claim altogether (as well as abandoning his contentions that Orthofix was required to have a contract with Medicare, and to use a unique cervical-stim billing code, as discussed further below). See Rel.’s Resp. to Mot. to Dismiss and Mot. to Am., Dkt. No. 102.



(“CMS”) fee schedule, or the provider’s actual charge to the patient for the item, whichever is lower. 42 U.S.C. § 1395m. Computation of the “national payment amount” does not require CMS to set that amount at the lowest cost any purchaser may have paid, *see id.* at (a)(2)(C), nor does the regulation setting reimbursement procedures for BGS contain any requirement that reimbursement be at the lowest price charged. *See* 42 C.F.R. § 414.220. Furthermore, while Medicare regulations do allow local Medicare carriers to adjust the fee schedule based on a “local payment amount,” these amounts are defined as the average reasonable charge to a patient, *as determined in 1990*, and increased by a yearly (fixed) update—they have never been tied to the lowest price paid by any purchaser, and have not considered what may be an “average charge” to a patient in nearly twenty years. *See* 42 C.F.R. § 414.220(d); *see also* 42 U.S.C. § 1395m(a)(2)(C).

Similarly, TRICARE does not limit reimbursement levels to the lowest price at which Orthofix sells its bone growth stimulators to other purchasers. Instead, like Medicare, TRICARE reimburses DME according to a fee schedule with the amount limited to the lower of the billed charge, a negotiated rate for network providers, or the CMS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (“DMEPOS”) fee schedule amount. 32 C.F.R. § 199.4(d)(3)(ii); TRICARE Reimbursement Manual 6010.58-M, ch. 1 § 11 (Feb. 1, 2008). For BGS in particular, TRICARE uses the reimbursement rates established by the DMEPOS fee schedule. *See TRICARE: Durable Medical Equipment, Prosthetics, Orthotics, & Supplies*, <http://www.TRICARE.mil/DMEPOS/> (last visited July 16, 2010).<sup>11</sup>

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<sup>11</sup> To the extent Counts 2–5 and 7–9 also allege violations of the FCA based on false claims submitted to Medicaid (in addition to Medicare and TRICARE), they fail to state a claim. While Relator treats Medicare and Medicaid as essentially the same program, in fact, Medicaid is a state-administered program under which each state sets its own guidelines regarding eligibility and services. 42 U.S.C. § 1396a *et seq.* Relator’s failure to identify any specific Medicaid

Because no law or regulation requires Orthofix to charge government programs the lowest price it charges other payers, the claims alleged in Count 2 and paragraph 41, which are premised on the existence of such a requirement, must be dismissed.

4. *Count 3 Should Be Dismissed Because Orthofix Was Not Required To Have a Contract with Medicare for a Specific Price for BGS*

The Relator alleges in Count 3 that Orthofix submitted false claims for payment to the government because Orthofix sought such reimbursement without having entered into a contract for the specific price charged for the units. SAC ¶ 47. Yet Relator again fails to point to any statute or regulation that requires such a contract. Nor can he, as, again, no such requirement exists. In fact, BGS suppliers like Orthofix do not contract with Medicare to set a particular reimbursement rate for BGS. *See supra* Part II.A.3. Instead, as noted above, Medicare and TRICARE reimbursement rates for BGS are capped at a fee schedule amount established unilaterally by CMS. *Id.* As a result, to the extent Count 3 relies on the absence of “a contract” for a specific reimbursement rate, Count 3 should be dismissed.

5. *Count 3 Should Also Be Dismissed Because a Unique Cervical-Stim Billing Code Is Not Required for Reimbursement*

Relator also asserts in Count 3 that Orthofix violated the FCA by submitting claims in the absence of an “individual code” for the Cervical-Stim BGS. SAC ¶ 47. Once again, however, there is no requirement that each variety of BGS, including the Cervical Stim, have its own individual code. Instead, BGS are covered as a *group* for specific medical indications. *See Medicare Nat’l Coverage Determination Manual* § 150.2 (Rev. 98, 12-24-08) (listing six

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program requirement for any specific state, or any alleged Orthofix action that violated such a requirement, is fatal to his Medicaid-based claims. *See generally Gagne*, 565 F.3d at 47 (holding that complaint failed where, among other problems, it did not identify laws violated or explain why actions were fraudulent); *United States ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F. Supp. 2d 938, 947 (N.D. Ill. 2009) (a court “is not required to hunt on its own” to identify source of alleged rules or procedures where relator failed to do so).

medical situations where osteogenesis (bone growth) stimulators are indicated); 32 C.F.R. § 199.4(d)(3)(ii); 32 C.F.R. § 199.2(b); TRICARE Policy Manual 6010.57-M, Chapter 8 § 2.1 (Feb. 1, 2008); TRICARE Policy Manual 6010.57-M, Chapter 4 § 6.2 (Feb. 1, 2008). As a result, Count 3 should be dismissed.

B. Count 4 Should Be Dismissed Because Relator Has Failed To Adequately Allege That Orthofix Instructed Physicians To Submit Claims for Services They Did Not Provide

Relator's Count 4 alleges that "many physicians have been encouraged by Orthofix to bill Medicare, Medicaid and TRICARE for fitting fees which were actually performed by Orthofix sales representatives or agents of Orthofix." SAC ¶ 49. Such conclusory assertions are insufficient to state a claim under either Rule 12(b)(6), *see Twombly*, 550 U.S. at 555; *Iqbal*, 129 S. Ct. at 1949–50 (allegations must state a plausible claim for relief, rather than "the mere possibility of misconduct"), or under Rule 9(b). Relator has still failed to identify a single physician who billed Medicare improperly; a sales representative who encouraged such billing; a facility at which any misconduct occurred; a patient involved; or any claim actually submitted. Instead, all he offers is a tangential allegation that he heard from fellow employee Trent Wood that such conduct occurred. SAC ¶ 28, 49. After four years, three complaints, and three briefs in which Orthofix identified these exact deficiencies, Relator has still failed to establish plausible factual grounds entitling him to relief. *See Iqbal*, 129 S. Ct. at 1949–50. Count 4 should therefore be dismissed.

C. Count 5 Should Be Dismissed Because Relator Has Failed To Allege a Violation of the False Claims Act Based on Illegal Kickbacks

In Count 5, Relator asserts that Orthofix violated the FCA by paying "illegal kickbacks" to providers, SAC ¶¶ 53–54, but pleads neither the necessary elements of an FCA violation nor sufficient supporting facts. It is axiomatic that, on their own, "alleged violations of federal

regulations are insufficient to support a claim under the FCA.” *Karvelas*, 360 F.3d at 234. Instead, the defendant must have “certifie[d] compliance with [that] statute or regulation as a condition to governmental payment.” *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001); *accord Karvelas*, 360 F.3d at 232. Here, Relator attempts to plead a violation of federal law—the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b—but fails to allege that Orthofix certified compliance with that statute as a condition of payment. Thus, without allegations of any “false” certification, Relator has failed to plead a cognizable claim under the FCA.

But even if Relator had pled the necessary elements of an FCA claim, his utter lack of factual allegations would still warrant dismissal under Rules 12(b)(6) and 9(b). The allegations of Count 5 itself, SAC ¶¶ 52–54, merely parrot the language of the Anti-Kickback Statute, and therefore fail to state a claim. *See Twombly*, 550 U.S. at 555. The SAC’s other allegation regarding referral fees asserts merely that Relator heard from Trent Wood that “it is *apparently* common practice in the industry, including Orthofix, for the field sales staff to pay a referral fee of \$50-\$150 to doctor’s administrative staff in order for the physician to prescribe an Orthofix BGS.” SAC ¶ 28 (emphasis added). But bare assertions about “apparent” practices do not substitute for *facts* that *show* that a defendant has violated the law. Relator fails to identify a single doctor’s office or sales representative engaged in wrongdoing, or a single referral obtained as a result. Absent such allegations, his claim should be dismissed. *Iqbal*, 129 S. Ct. at 1949–50; *Karvelas*, 360 F.3d at 230, 233.

D. Count 7 Should Be Dismissed Because Relator Has Failed To Allege an Agreement To Defraud the Government by Filing False Claims

Count 7’s conclusory allegations fail to establish the existence of any agreement giving rise to a conspiracy. To plead a violation of section 3729(a)(3), a relator must allege facts that support the existence of an unlawful agreement between two parties to get a false or fraudulent

claim paid by the United States, and allege that a party performed at least one act in furtherance of that aim. *See United States v. President and Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 196 (D. Mass. 2004); *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005).

Furthermore, a relator must plead these elements with the specificity required by Rule 9(b).

*Gagne*, 565 F.3d at 45. Relator's SAC does not meet these standards.

Relator alleges that “[e]very time Orthofix enters into an agreement or arrangement with a physician” to seek payment for fittings the physician did not perform, “the physician and Orthofix have conspired to submit a false claim.” SAC ¶ 60. This allegation, however, states no more than a legal conclusion, which cannot sustain the claim. *Iqbal*, 129 S. Ct. at 1950. Nor do Relator's other allegations offer any factual support for this conclusory allegation. For example, despite his assertion that Orthofix violates the FCA “[e]very time” it enters into agreements with physicians, Relator fails to identify *a single time* Orthofix allegedly entered into such an agreement. Nor has he identified a single physician who was supposedly involved. Moreover, even if Relator did identify a physician who billed improperly, he would still have failed to plead that Orthofix agreed that the physician should do so. Without allegations that show the existence of an agreement to pursue an unlawful claim, Relator fails to plead an essential element of a conspiracy. *Corsello*, 428 F.3d at 1014 (upholding dismissal of FCA conspiracy claim where “bare legal conclusion was unsupported by specific allegations of any agreement or overt act,” even though—unlike here—the parties to the alleged agreement were identified). Accordingly, Count 7 should be dismissed.

### III. COUNT 6 SHOULD BE DISMISSED BECAUSE RELATOR HAS NOT ALLEGED A CLAIM FOR WRONGFUL TERMINATION

Relator's SAC similarly fails to allege a claim for wrongful termination under the FCA. Such a claim requires a plaintiff to allege each of three distinct elements: (1) that the plaintiff

engaged in protected conduct; (2) that the defendant knew of that protected conduct; and (3) that the defendant terminated the plaintiff because of that protected conduct. *Karvelas*, 360 F.3d at 235. Once again, despite numerous opportunities to cure this defect, and repeated briefings from Orthofix pointing out the shortcomings in his prior filings,<sup>12</sup> Relator has failed adequately to allege these elements.

According to the First Circuit, “protected conduct” is conduct that “reasonably could lead to a viable FCA action,” *Karvelas*, 360 F.3d at 236; “in other words, investigations, inquiries, testimonies or other activities that concern the employer’s knowing submission of false or fraudulent claims for payment to the government,” *id.* at 237. Here, however, rather than alleging specific affirmative actions that Relator took to “investigate” fraud against the government, the SAC merely describes conversations in which Relator’s colleagues expressed to him their concerns about the legality of certain conduct or practices, SAC ¶¶ 19–21, 25, 26, 28–29; sets out what other Orthofix employees happened to do in Relator’s presence, *id.* ¶ 16; or addresses noncompliance with contracts with private payers—not *fraud* on the *government*, *id.* ¶¶ 16, 17, 23, 25, 30. None of these allegations constitutes protected conduct. *See Karvelas*, 360 F.3d at 237 (requiring allegations of fraud, rather than of “noncompliance with state or federal regulations”); *Gublo*, 62 F.Supp. 2d at 356 (“[T]he plaintiff must demonstrate that her investigation, inquiries and/or testimony were directed at exposing fraud upon the government.”). Nor has Relator satisfied the second element of his claim—that Orthofix knew Relator was engaged in such conduct. Relator never alleges that he informed anyone at Orthofix that he was “investigating” fraud on the government or that Orthofix was otherwise aware of any

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<sup>12</sup> *See* Mot. to Dismiss Am. Compl., at 20–21, Dkt. No. 91; Def.’s Opp. to Rel.’s Mot. to Am. Compl. at 11–13, Dkt. No. 116; Reply to Resp. Mot. to Dismiss Am. Compl. at 5–6, Dkt. No. 118.

such conduct. Instead, Relator's allegations paint a picture of an employee who was the passive recipient of complaints from his colleagues, and who engaged in a limited, discreet review of materials relating to private payers, without informing anyone of his supposed concerns about fraud on the government.

Moreover, even if Relator had satisfied the first two elements of his FCA wrongful termination claim, he utterly fails to plead the final causation element. As First Circuit law makes clear, conclusory recitations of the elements are not sufficient to state a wrongful termination claim. *Karvelas*, 360 F.3d at 240 (noting, in finding that plaintiff had not satisfied the causation element, that "simply parroting the language of a statutory cause of action, without providing some factual support, is not sufficient to state a claim"). But this is all Relator's SAC offers—boilerplate assertions that, for example, "Orthofix fired Laughlin to prevent him from uncovering, exposing and attempting to stop illegal activity," SAC ¶ 56, or "Orthofix fired Laughlin due to his investigation of the illegal acts of Orthofix, and his efforts to stop such actions," *id.*, without alleging any supporting facts. As such, Relator has failed to sustain his burden on this element. *See Karvelas*, 360 F.3d at 240 (dismissing an FCA wrongful termination claim because plaintiff had failed to "allege a factual predicate concrete enough to support his conclusory statement that he was retaliated against because of conduct protected under the FCA"). Because Relator has failed to adequately allege any of the elements of this claim, it should be dismissed.

#### IV. COUNTS 10–56 SHOULD BE DISMISSED BECAUSE THEY DO NOT STATE A CAUSE OF ACTION AND BECAUSE JURISDICTION-SPECIFIC PROCEDURAL PROVISIONS PRECLUDE RELATOR'S CLAIMS

Relator has now asserted forty-seven tag-along counts under twenty-five state false claims acts and two municipal false claims acts. As discussed above, these claims fail to satisfy Rule 9(b), and should be dismissed on that ground alone. *See supra* Part I. In addition, Relator

does not explain or identify what Medicaid or other unidentified local healthcare program rules or regulations were allegedly violated by Orthofix—let alone allege facts that show how, or by whom they were violated. For these reasons, and because jurisdiction-specific procedural provisions also preclude Relator’s claims, Counts 10–56 should be dismissed.

A. Relator’s Claims Under State and Local Law Should Be Dismissed Because He Has Not Alleged Any Violation of State or Local Program Requirements

Relator’s state and local FCA causes of action fail because he has not alleged false claims, prohibited acts, or even theories of liability under any state or local healthcare program. Relator does not even attempt to plead facts to support these claims, and relies instead on his minimal and inadequate allegations that Orthofix violated federal Medicare program requirements. This is patently insufficient. In addition to failing the requirements of Rules 9(b) and 8(a), the SAC’s assumption that such assertions also allege a violation of any state’s Medicaid or other healthcare program requirements has no basis in law. In fact, as observed in a different context, “Medicare and Medicaid are entirely separate programs with different purposes and standards. . . . Federal Medicare enactments do not provide any mandates for state Medicaid practices.” *Evanston Hosp. v. Hauck*, No. 92-732, 1992 WL 205900, at \*2 (Aug. 19, 1992). There is no one “Medicaid” procedure for coverage and reimbursement; rather, each state sets its own guidelines regarding eligibility and services. 42 U.S.C. § 1396 *et seq.* Relator explains neither the varying reimbursement guidelines for any particular state Medicaid (or any other) program, nor how Orthofix’s alleged conduct violates any particular such guideline. This failing is fatal to his state and local claims, and they should therefore be dismissed. *See supra* n.11.

B. Relator’s State and Local Claims Should Be Dismissed Because Jurisdiction-Specific Procedural Provisions Prevent Relator from Stating a Claim

Besides his failure to allege violations of any state or local healthcare program, several jurisdiction-specific provisions of these laws also prevent Relator from pleading valid causes of



action. First, Relator cannot state a claim under twenty-two of these laws because the docket shows that those jurisdictions have not elected whether to intervene within the statutory time frame, a necessary prior step before a relator may conduct an action.<sup>13</sup> In addition, many of the state and local laws Relator invokes have effective dates that postdate the alleged misconduct, and thus cannot provide Relator with a cause of action.<sup>14</sup> Similarly, the applicable statutes of limitations preclude Relator from seeking remedy under the New Mexico and Texas false claims acts.<sup>15</sup> Finally, Relator cannot bring claims under Chicago or New York City law because the proper entities are not parties.<sup>16</sup>

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<sup>13</sup> Cal. Gov't Code § 12652(c)(6); 6 Del.C. § 1203(b)(4); D.C. Code § 2-308.15(b)(4); Fla. Stat. § 68.083(6); Ga. Code Ann. § 49-4-168.2(c)(4); Haw. Rev. Stat. § 661-25(d); 740 Ill. Comp. Stat. 175/4(b)(4); Mass. Gen. L. ch. 12, § 5C(4); Mich. Comp. Laws § 400.610a(3); Minn. Stat. § 15C.06(a); N.H. Rev. Stat. § 167:61-c(II)(e); N.J. Stat. Ann. § 2A:32C-5(g); N.M. Stat. § 27-14-7(C); N.Y. State Fin. Law § 190(2)(c), (2)(f); Okla. Stat. tit. 63 § 5053.2(B)(4); R.I. Gen. Laws § 9-1.1-4(b)(4); Tenn. Code § 4-18-104(c)(6); Tenn. Code § 71-5-183(b)(4); Tex. Hum. Res. Code § 36.104; Va. Code § 8.01-216.5(D); Wis. Stat. § 20.931(5)(d); Chicago Mun. Code ch. 1-22-030(b)(4); NYC Admin. Code § 7-804(b)(2)–(3). Counts 10–23, 28–30, 33–51, 53–56.

In addition, although some of these jurisdictions allow a relator to proceed even if the state or municipality declines to do so, four preclude a relator from proceeding unless either (a) the state or municipality affirmatively gives permission, N.M. Stat. § 27-14-7(C), (E) and NYC Admin. Code § 7-804(b)(2), Counts 35–36, 49–50, or (b) the state itself intervenes, N.H. Rev. Stat. Ann. § 167:61-c(II)(e) (amended 2009) (applying to claims before 2009) and Tex. Hum. Res. §§ 36.102(c), 36.104(b) (amended 2007) (applying to claims before 2007), Counts 33–34, 43–44.

<sup>14</sup> Ga. Code Ann. § 49-4-168–168.6 (effective May 24, 2007); Minn. Stat. § 15C.01–.16 (effective July 1, 2010); N.J. Stat. Ann. § 2A:32C-1–18 (effective Mar. 13, 2008); N.Y. State Fin. Law § 187–194 (effective Apr. 9, 2007); Okla. Stat. tit. 63 § 5053.1–7 (effective Nov. 1, 2007); R.I. Gen. Laws § 9-1.1-1–8 (effective July 1, 2007); Wis. Stat. § 20.931 (effective Oct. 27, 2007). Counts 19, 37–38, 51, 53–56.

<sup>15</sup> See N.M. Stat. §§ 27-14-13(A), 37-1-4 (four years); Tex. Hum. Res. Code § 36.101, *et seq.* (see *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 817–18 (E.D. Tex. 2008) (four years). Counts 35–36, 43–44.

<sup>16</sup> Chicago Mun. Code ch. 1-22-030(b)(1) (only city contractors may be *qui tam* defendants); NYC Admin. Code § 7-804(e) (only plaintiffs expressly authorized by the Corporation Counsel may file suit). Counts 47–50.

V. RELATOR’S SAC SHOULD BE DISMISSED WITHOUT LEAVE TO REPLEAD

The Court should dismiss Relator’s SAC without leave to amend. While leave to amend should be freely granted “when justice so requires,” Fed. R. Civ. P. 15(a), a court may—and should—deny leave to replead where, as here, any additional amendment would be futile or would reward undue delay. *Foman v. Davis*, 371 U.S. 178, 182 (1962) (explaining that reasons for denying leave to amend include “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.”); *Gagne*, 565 F.3d at 48 (citing *Foman*).

First, Relator has already had four distinct opportunities to author an adequate pleading: his initial complaint; his FAC; the opportunity (albeit ultimately declined) to amend prior to service on defendants; and the SAC at issue here. Nevertheless, he has failed each time. Furthermore, several of Relator’s claims cannot be cured no matter how many opportunities he is offered—as set out above, Part II.A., there is no legal basis for Counts 1–3, and Count 1 is jurisdictionally barred. Under these circumstances, leave to replead yet again would be futile, and should be denied. *See Gagne*, 565 F.3d at 48 (affirming lower court’s denial of leave to file third amended complaint, which was “based on relators’ repeated failure to cure the deficiencies in their pleadings,” and noting that “plaintiffs do not get a fourth chance to get it right”); *Corsello*, 428 F.3d at 1014 (affirming denial of leave to file third amended complaint, citing plaintiff’s repeated failure, despite prior warnings, to cure Rule 9(b) deficiencies in past amendments).

Finally, allowing another amendment would reward a relator whose pleading history reflects deliberate delay tactics. Indeed, despite Orthofix’s stated concerns about this very

issue,<sup>17</sup> Relator used his SAC solely to add factual allegations that could have been included in Relator's FAC, if not in the original complaint itself, and to add forty-seven new boilerplate unsubstantiated state and local false claims act counts. This sort of deliberate delay tactic should not be countenanced. *See Gagne*, 565 F.3d at 48 ("Reasons for denying leave include undue delay . . . or dilatory motive . . ."); *Hayes v. New England Millwork Distribs., Inc.*, 602 F.2d 15, 19–20 (1st Cir. 1979) (holding, following years of briefing and discovery, "where, as here, a considerable period of time has passed between the filing of the complaint and the motion to amend . . . the movant [must] show some 'valid reason for his neglect and delay'"); *United States ex rel. Driscoll v. Serono Inc.*, No. 00-11680, 2008 WL 728939, at \*4 & n.2 (D. Mass. Mar. 18, 2008) (refusing leave to amend where relators had been on notice of *Karvelas*' Rule 9(b) standard, and had failed to allege sufficient detail to meet Rule 9(b) despite having years, and subsequent amended complaints, to do so).

Relator has had ample opportunity to plead a viable claim. He has not, and the pleading history, and the nature of several of his claims, make clear that further amendment would be futile, and that it would reward four years of delay and inaction. Rather than force Orthofix, and this Court, to undergo yet another round of costly and ultimately pointless briefing, Relator's SAC should be dismissed with prejudice.

### CONCLUSION

For all of the foregoing reasons, Orthofix requests that the Court grant this motion, with prejudice, and dismiss Relator's Second Amended Complaint in its entirety.

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<sup>17</sup> See Def.'s Opp. to Rel.'s Mot. to Am. Compl. at 15-16, Dkt. No. 116.

Dated: July 23, 2010

Respectfully submitted,

ROPES & GRAY LLP

By: /s/ Kirsten V. Mayer

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**CERTIFICATE OF CONFERENCE**

Pursuant to Local Rule 7.1, I hereby certify that counsel for the Defendant has reached out to Relator's counsel by phone and email in good faith today to discuss resolving or narrowing the issues presented by this motion to dismiss but was unable to confer before filing. Defense counsel will confer with Relator's counsel as soon as that can occur.

Dated: July 23, 2010

By: /s/ Kirsten V. Mayer

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**CERTIFICATE OF SERVICE**

I hereby certify that these documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on July 23, 2010.

Dated: July 23, 2010

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